REMARKS

Claims 1-13 are pending. Applicant respectfully requests reconsideration of this application in view of the following remarks.

I. Written Description

Claims 1-3 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking a written description with respect to treatment of "a detected apnea or hypopnea" (Action at 2). We respectfully traverse.

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2s 1614, 1618 (Fed.Cir. 1989)("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.")

Important here is that the specification need only "contain an equivalent description of ... claimed subject matter." Lockwood, at 1572. Claimed subject matter need not be described in haec verba to satisfy the requirement. In re Smith, 481 F.2d 910, 914 (C.C.P.A. 1973); Lockwood, at 1572. An inherent disclosure is sufficient, provided that any missing descriptive matter is "present in the ... specification such that one skilled in the art would recognize such a disclosure." In re Smith, at 914.

The Examiner's attention is respectfully directed to Applicants' specification, which states in relevant part:

> The starting point of this invention lies in the observation by the inventors that a **systematic increase of the heart rate** in response to a detection of **apnea or hypopnea**

> is **not always a suitable *treatment***. Indeed, it has been reported that for certain patients the apnea or hypopnea could be followed by an adrenergic reaction. Such a reaction naturally induces a light tachycardia and a significant increase in blood pressure, sufficient to compensate for the fall of the ventilatory activity. Among these patients, the myocardium thus can react naturally by adapting its contractility so as to increase the blood flow. In this way, the myocardium maintains the blood appreciably at the same level of oxygen saturation.
>
> Ideally, to decide whether or not it is necessary to apply to the myocardium a stimulation at a frequency higher than the natural sinusal rate/rhythm of the patient, the best criterion would be a direct measurement of oxygen saturation in blood. Then, the stimulation would be started only in the event of a proven and significant desaturation. But such a direct measurement of oxygen saturation is difficult to implement in a simple and permanent manner in the context of an active implanted medical device, given the current state of the art.
>
> **Objects and Summary of the Invention**
>
> Broadly, the present invention proposes to overcome **the aforementioned deficiency in the *treatment* of the apnea and the hypopnea** by estimating variation of contractility of the myocardium by use of an hemodynamic sensor. Thus, in the event of a detected anomaly in the respiratory activity (i.e., **an apnea or hypopnea**), **before taking any therapeutic action**, the device estimates whether or not there was a correlative modification of the myocardium contractility.

(Specification at 2-3) (emphasis supplied). We respectfully submit that a person of ordinary skill in the art would understand from reading at least the above-quoted portion of Applicants' specification that there is an unambiguous written description to treat apnea (e.g., a SAS or Sleep Apnea Syndrome) and hypopnea. Specifically, Applicants disclosed in writing that "a systematic increase of the heart rate in response to a detection of an apnea or hypopnea is not always a suitable treatment", thereby telling persons skilled in the art that the invention disclosure is directed to a solution to this treatment problem, a more suitable "treatment" of such a detected apnea or hypopnea.

Further, the specification describes taking "therapeutic action" or an "action" (i.e., a treatment) in response to an apnea or hypopnea in combination with the significant contractility

measure, to provide a suitable treatment of that detected apnea or hypopnea (e.g., Specification at 2).

Moreover as noted, the applicable law does not require that the claim language appear *in haec verba* in the specification to satisfy the written description requirement, although Applicants submit that it essentially is so found here, so long as there is equivalent or inherent, and would be so understood by a person of ordinary skill in the art.

In view of the foregoing, we respectfully submit that Applicants have provided a sufficient written description for the claimed subject matter and that the Examiner's rejections under § 112 should be withdrawn.

II. 35 U.S.C. § 102(b) Rejection

In the Office Action dated August 15, 2007, claims 1-5 and 11-13 were rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Street (EP 1 151 718 A2). Claims 6-7 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Street in view of Hartley (US 6,161,042). Claim 8 was rejected under 35 U.S.C. § 103(a) as being rendered obvious by Street in view of Bonnet (US 6,574,507). Claims 9-10 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Street. Applicant respectfully traverses the ground for these rejections below.

"[A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas Techs., Ltd. v. Rockwell Int'l. Corp.*, 150 F.3d 1354, 1361, 47 U.S.P.Q.2d 1516, 1522 (Fed. Cir. 1998). The standard for lack of novelty, that is, for "anticipation," is one of strict identity. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296, 63 U.S.P.Q.2d 1597, 1600 (Fed. Cir. 2002).

Although the Examiner is correct that Street discloses an apparatus for monitoring periodic breathing as an indication of changes in the hemodynamic status of the heart, Street does not teach or suggest any functionality or structure for using the data acquired during monitoring to actually treat a detected apnea or hypopnea when said detected contractility variation is significant, as called for in claim 1. Rather, Street teaches to treat a different indication, namely, congestive heart failure, by ACE inhibitors, diuretics, digitalis, heart transplant, aerobic exercise or cardiac pacing. *See* Street [0006]-[0007]. Thus, because Street fails to disclose each and every element in claim 1, the Examiner's rejection should be withdrawn.

In addition, Street does not teach or suggest to use the combination of a detected apnea or hypopnea and a significant contractility variation to conditionally modify any operating parameter to treat the detected apnea or hypopnea, as required by claim 1. The Examiner correctly notes that Street teaches various techniques ("any of four physiologic parameters"; Action at 4) to identify when a Periodic Breathing condition exists. A Periodic Breathing event can then be used -- in an unexplained and non-enabled manner -- "to recognize and facilitate the early termination of a developing exacerbation [citation omitted]" (Action at 3) of a cardiac insufficiency -- i.e., congestive heart failure. However, the Examiner nowhere indicates where in Street it discloses determining a contractility variation, let alone where it is a **significant** contractility variation. We submit that this is because there is none.

The Examiner referred to Street Fig. 2 as teaching "the contractility variation is analyzed before and after detection of hypopnea". We respectfully disagree. As we understand Street, a plain reading of the description of Fig. 2 demonstrates that what is depicted in Fig. 2 is no more

than determining whether a Periodic Breathing condition exists in a particular embodiment. Street [0029]-[0036]. Nowhere does Street teach or suggest to combine a detected apnea or hypopnea with a determined significant contractility variation to conditionally modify an operating parameter to treat a detected apnea or hypopnea. For this additional reason, the Examiner's rejection of claim 1 should be withdrawn.

Claims 2-13 depend from claim 1 and are allowable for at least the same reason that claim 1 is allowable. Accordingly, claims 2-13 also should be allowed.

III. 35 U.S.C. § 103(a) Rejections

Dependent claims 6-7 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Street in view of Hartley (US 6,161,042), dependent claim 8 was rejected under 35 U.S.C. § 103(a) as being rendered obvious by Street in view of Bonnet (US 6,574,507), and dependent claims 9-10 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Street. We respectfully traverse.

To establish a *Prima Facie* case of obviousness, there must be: (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine references teachings; (2) a reasonable expectation of success; and (3) prior art references which teach or suggest all of the claim limitations. *See In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000); MPEP § 2143 (8th Ed., Rev. 1). As discussed above, Street fails to disclose the means element found in independent claim 1 for "conditionally modifying an operating parameter of the device to treat a detected apnea or hypopnea when said detected contractility variation is significant." Moreover, Bonnet and Hartley, the secondary references cited by the Examiner in this Office action, both

fail to disclose this feature, and thus do not cure the deficiency of the primary reference. Thus, Street, when considered alone or in combination with either Bonnet or Hartley, or both, fails to disclose all the elements taught in amended claim 1.

Furthermore, none of the references would motivate one to modify any of the other references to include this functionality. Although Street discloses monitoring periodic breathing, none of the references disclose any means for applying a therapy to treat the apnea or hypopnea as claimed in claim 1. Indeed, Hartley discloses a rate adaptive cardiac rhythm management device that fails to address the issue of periodic breathing. Bonnet discloses a method for treating apneas, but fails to disclose any method or functionality for detecting and treating hypopneas. And, as discussed above, Street only discloses an apparatus and method for monitoring periodic breathing and fails to disclose any functionality or structure for applying a therapy when changes are detected. Here, the prior art references, even when combined, and we submit that there is no proper basis to combine them, provide no suggestion of desirability in making the combination as evidenced by their failure to disclose all of the elements taught in amended claim 1.

For the foregoing reasons, Applicant respectfully asks the Examiner to reconsider and withdraw the §103(a) rejections noted above.

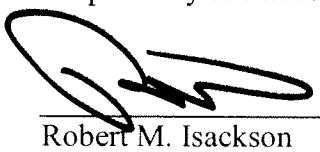
CONCLUSION

Applicant respectfully submits that they have made a patentable contribution to the art. Reconsideration of this application in view of the foregoing remarks respectfully is requested.

The Examiner is invited to call Applicants' undersigned attorney if doing so would expedite prosecution.

Date: February 13, 2008

Respectfully submitted,



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